

Remarks

This application has been carefully reviewed in light of the Office Action dated June 26, 2009. Claims 1-3, 5-16, 18-26, and 28-40 are currently in the application, with claims 1-3, 5-15, 29 and 36 having been withdrawn from consideration. Claims 16 and 40 are the independent claims currently under consideration. Reconsideration and further examination are respectfully requested.

Claims 16, 18-20, and 26 have been amended herein. Support for this amendment may be found at least on page 8, lines 8-41, of the specification. No new matter is believed to have been added to the application by way of this amendment.

Claim Rejections - 35 U.S.C. § 102

Claims 16, 18-20, 23, 24, 26, 28, 31, 35, and 40 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,552,751 ("Inaba"). Applicant has reviewed the applied reference and respectfully submits that the claimed invention is patentably distinguishable over the applied reference for at least the following reasons.

Independent claim 16 is directed to a film produced by a method of forming a non-gelatin polymeric film, applying a liquid transport medium to one or more surfaces of the film, the liquid transport medium incorporating at least one active ingredient, and allowing the liquid transport medium applied to at least partially cure and associate with the film. The film produced by this method results in the at least one active ingredient being absorbed within the film, wholly or partially, and forming a homogeneous polymer film product.

As indicated above, independent claim 16 has been amended to specify that a liquid transport medium incorporating at least one active ingredient is applied to a non-gelatin

polymeric film resulting in the at least one active ingredient being absorbed within the film. Inaba is not seen to disclose or even suggest these features of the claimed invention.

Inaba describes a multi-layered film preparation that includes at least two drug release controlling layers with at least one drug storing layer between the two drug release controlling layers. *See* Inaba, col. 2, lines 51-55. According to one process described in Inaba, a drug storing layer solution is coated on a film obtained from drying a drug release controlling layer solution and subsequently dried to prepare respective film-formed layers. *See* Inaba, col. 5, lines 18-24. The Office Action contends that the multi-layered film preparation described in Inaba anticipates the structure of the film produced by the steps recited in independent claim 16. Applicant respectfully disagrees.

Inaba is silent regarding the interaction between the components of the drug storing layers and the components of the drug release controlling layers. More particularly, Inaba is silent regarding the transport of the drug contained in the drug storing layers to the drug release controlling layers and the absorption therein. Arguably, Inaba teaches away from such an interaction between the layers in the multi-layered film preparation since allowing the drug to be transported from the drug storing layers and absorbed within the drug release controlling layers would defeat the respective purposes of these layers.

Independent claim 16, on the other hand, specifies that a liquid transport medium incorporating at least one active ingredient is applied to a non-gelatin polymeric film. By allowing the liquid transport medium to at least partially cure and associate with the non-gelatin polymeric film, the at least one active ingredient is absorbed within the non-gelatin polymeric film forming a homogenous polymer film product. Inaba's multi-layered film preparation is not seen to involve the transport of an active ingredient between layers, let alone the absorption of an

active ingredient from a drug storing layer into a drug release controlling layer. Accordingly, the structure implied by the method steps recited in claim 16 is not anticipated by the multi-layered film preparation described in Inaba.

Therefore, independent claim 16 is believed to be allowable over Inaba. Reconsideration and withdrawal of the § 102(b) rejection of independent claim 16 are respectfully requested.

Independent claim 40 is directed to a non-gelatin polymeric film wherein the film includes two or more bands. At least one active ingredient is dispersed within a particular band. The film is a single film with structural homogeneity between the bands.

Inaba describes a multi-layered film preparation formed by either mounting prepared films on one another using a dry laminate or a wet laminate method, or coating a prepared film with a layer solution, which is subsequently dried to form a layer on the prepared film. The Office Action contends that each layer of Inaba's multi-layered film is casted together to form a continuous structure. However, nothing in Inaba is seen to describe each layer in the multi-layered film as being cast together. Rather, as mentioned above, each layer used in Inaba's multi-layered film is seen to be cast individually. Furthermore, nothing in Inaba is seen to describe, nor has the Office Action cited any portion of Inaba describing, the multi-layered film having structural homogeneity between the individually formed layers of the multi-layered film.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Inaba is not seen to describe a single film comprising two or more bands with structural homogeneity between the bands.

Therefore, independent claim 40 is believed to be allowable over Inaba. Reconsideration and withdrawal of the § 102(b) rejection of independent claim 40 are respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 25 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent Application Publication No. 2003/0183643 (“Fagen”). Claims 21, 22, and 37-39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent Application Publication No. 2004/0253434 (“Patel”). Claim 30 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent No. 6,783,768 (“Brown”). Claims 33 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of Fagen and further in view of U.S. Patent No. 7,112,361 (“Lynn”).

Claims 21, 22, 25, 30, 32-34, and 37-39 are dependent from independent claim 1 discussed above. None of the references applied in the § 103 rejections are seen to disclose or suggest anything to remedy the deficiencies of the Inaba reference discussed above. Therefore, claims 21, 22, 25, 30, 32-34, and 37-39 are believed to be allowable over the applied references for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, however, the individual consideration of each on its own merits is respectfully requested.

Conclusion

The absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be other reasons for patentability of any or all claims that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this

paper, and the amendment or cancellation of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment or cancellation.

In view of the foregoing remarks, the claims currently under consideration are believed to be in condition for allowance and such action is respectfully requested at the Examiner's earliest convenience.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502203 and please credit any excess fees to such deposit account.

Respectfully submitted,

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